

## Medical Information Privacy and Security Act (H.R. 1057)

### Section-by-Section Analysis

#### 106th CONGRESS

Representative Edward J. Markey introduced the Medical Information Privacy and Security Act (MIPSA) on March 10, 1999. The purpose of the bill is to provide individuals with access to health information of which they are a subject, ensure personal privacy with respect to health-care information, impose criminal and civil penalties for unauthorized use of protected health information, to provide for the strong enforcement of these rights, and to protect States rights.

#### TITLE

Sec.1. This Act may be cited as the "Medical Information Privacy and Security Act".

#### FINDINGS

Sec.2. The Congress finds that:

- Individuals have a right of privacy with respect to their protected health information and records.
- With respect to information about medical care and health status, the traditional right of confidentiality (between a health care provider and a patient) is at risk.
- An erosion of the right of privacy may reduce the willingness of patients to confide in physicians and other practitioners and may inhibit patients from seeking care.
- An individual's privacy right means that the individual's consent is needed to disclose his or her protected health information and that the individual has a right of access to that health information.
- Any disclosure of protected health information should be limited to that information or portion of the medical record necessary to fulfill the immediate and specific purpose of the disclosure.
- Health research often depends on access to both identifiable and de-identified patient medical records and medical research is critically important to the health and well-being of all Americans;
- the Supreme Court found in *Jaffee v. Redmond* (1996) that there is an imperative need for confidence and trust between a psychotherapist and a patient which can only be established by an assurance of confidentiality and that preservation of such trust and confidentiality serves the public interest by facilitating the provision of appropriate treatment for individuals; and
- Section 264 of the Health Insurance Portability and Accountability Act of 1996) establishes a deadline that Congress enact legislation, before August 21, 1999, to protect the privacy of protected health information.

#### PURPOSES

Sec. 3. It is the purpose of this Act to:

- recognize that there is a right to privacy with respect to health information, including genetic information, and that this right must be protected;
- create incentives to turn protected health information into de-identifiable health information where appropriate;
- to designate an Office of Health Information Privacy within the Department of Health and Human Services to protect that right of privacy;
- provide individuals with access to health information of which they are the subject, the right to supplement records if the information if such record is inaccurate or incomplete;
- provide individuals with the right to limit the use and disclosure of protected health information; and
- establish strong and effective mechanisms to protect against the unauthorized and inappropriate use of personally identifiable health information and strong and effective remedies for violations of this Act.
- protect States rights.

**Sec. 4 SELECTED DEFINITIONS**

Sec. 4(3)(A) -- "*De-identified health information*" means any protected health information, with respect to which all personal identifiers, or other information that may be used by itself or in combination with other information which may be available to re-identify the subject of the information, have been removed; and a good faith effort to evaluate the risks of re-identification of the subject of such information in the context in which it will be used or disclosed, has been made.

Sec. 4(3)(B) *Examples of De-identified health information*--The term includes aggregate statistics, redacted health information, information in which random or fictitious alternatives have been substituted for personally identifiable information, and information in which personally identifiable information has been encrypted and the decryption key is maintained by a person otherwise authorized to have access to such protected health information in an identifiable format.

Sec. 4(4) *Disclose*--The term "disclose" means to release, publish, share, transfer, transmit, disseminate, show, permit access to, re-identify, or otherwise divulge protected health information to any person other than the individual who is the subject of such information. The term includes the initial disclosure and any subsequent redisclosure of protected health information.

Sec. 4(5) *Decryption key*--The term "decryption key" means the variable information used in or produced by a mathematical formula, code, or algorithm, or any component thereof, used to encrypt or decrypt wire or electronic communications or electronically stored information.

Sec. 4(16) *Person*--The term "person" means a government, governmental subdivision of an executive branch agency or authority; corporation; company; association; firm; partnership; society; estate; trust; joint venture; individual; individual representative; tribal government; and any other legal entity.

Sec.4(17) *Protected Health Information*--The term "protected health information" means any information, including genetic information, demographic information, and tissue samples collected from an individual, whether oral or recorded in any form or medium, that:

- is created or received by a health care provider, health researcher, health plan, health oversight agency, public health authority, employer, health or life insurer, school or university;
- relates to the past, present, or future physical or mental health or condition of an individual (including individual cells and their components), the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual; and
- identifies an individual; or with respect to which there is a reasonable basis to believe that the information can be used to identify an individual; the term includes the decryption key

Sec.4(19) *Re-identify*--The term "re-identify", when used with respect to de-identified health information, means an attempt, successful or otherwise, to ascertain the identity of the individual who is the subject of such information; or the decryption key with respect to the information (when undertaken with knowledge that such key would allow for the identification of the individual who is the subject of such information).

Sec.4(24) *to the Maximum Extent Practicable*--The term *to the maximum extent practicable* means the level of compliance that a reasonable person would deem technologically feasible so long as such feasibility is periodically evaluated in scientific advances.

## **TITLE I--INDIVIDUALS' RIGHTS**

### **Subtitle A--Access to Protected Health Information by Subjects of the Information.**

This subtitle permits individuals with access to their protected health information for the purposes of inspection, copying and supplementing.

#### **Inspection and Copying of Protected Health Information**

Sec.101(a)(1) *Right of Individuals--In General*--A health care provider, health plan, employer, health or life insurer, school, or university, or a person acting as the agent of any such person, shall permit an individual who is the subject of protected health information, or the individual's designee, to inspect and copy protected health information concerning the individual, including records created under sections 102, 112, 202, 203, 208, and 211, that such person maintains.

Sec.101(a)(2) *Right of Individual Procedures and fees.* A person described in paragraph (1) may set forth appropriate procedures to be followed for inspection and copying under such paragraph and may require an individual to pay fees associated with such inspection and copying in an amount that is not in excess of the actual costs of providing such copying. Such fees may not be assessed where such an assessment would have the effect of inhibiting an individual from gaining access to the information described in paragraph (1).

Sec.101(b) *Right of Individuals Deadline*--A entity described in subsection (a) shall comply with a request for inspection or copying of protected health information not later than 15 business days after the

date on which the person receives the request.

**Sec.101(c) Rules Governing Agents**--A person acting as the agent of the entity described in subsection (a) shall provide for the inspection and copying of protected health information if the protected health information is retained by the agent; and the agent has been asked by the person involved to fulfill the requirements of this section.

**Sec.101(d) Special Rule Relating to Ongoing Clinical Trials** With respect to protected health information that is created as part of an individual's participation in an ongoing clinical trial, access to the information shall be provided consistent with the individual's agreement to participate in the clinical trial.

## **Sec. 102. Supplements to Protected Health Information.**

**Sec.102(a) In General**--Within 45 days of receiving a written request from an individual to supplement information, a health care provider, health plan, employer, health or life insurer, school, or university, shall add the supplement requested to the records; inform the individual of the supplement that has been added; and make reasonable efforts to inform any person to whom the portion of the un-supplemented information was previously disclosed, of any substantive supplement that has been made.

**Sec.102(b) Refusal to Supplement**--If a person declines to make the supplement requested, the person shall inform the individual in writing of the reasons for declining to make the supplement; any procedures for further review; and the right to file a concise statement on the requested supplement and reasons for disagreeing with the declining person and the right to include a copy of this refusal in his or her health record.

**Sec.102(c) Statement of Disagreement**--If an individual has filed a statement of disagreement under subsection (b), the entity involved, in any subsequent disclosure of the disputed portion of the information shall include, at the individual's request, a copy of the individual's statement; and may include a concise statement of the reasons for not making the requested supplement.

**Sec.102(d) Rules Governing Agents**--The agent of an entity described in subsection (a) shall not be required to make supplements to protected health information, except where the protected health information is retained by the agent and has been asked by such entity to fulfill the requirements of this section.

## **Notice of Privacy Practices**

**Sec.103(a) Preparation of Written Notice**--A health care provider, health plan, health oversight agency, public health authority, employer, health or life insurer, school, or university shall prepare a written notice of the privacy practices of the person that shall include:

- (1) the procedures for an individual to authorize disclosures of protected health information, and the procedures to object to, modify, and revoke such authorizations;
- (2) the right of an individual to inspect, copy, and supplement the protected health information;
- (3) the right of an individual not to have employment or the receipt of services conditioned upon the execution by the individual of an authorization for disclosure;

- (4) a description of the categories or types of employees, by general category or by general job description, who have access to or use of protected health information within the entity;
- (5) a simple, concise description of any information systems used to store or transmit protected health information, including a description of any linkages made with other electronic systems or databases outside the person;
- (6) the right of the individual to request segregation of protected health information and to restrict the use of such information by employees, agents, and contractors of an entity;
- (7) the circumstances under which the information may be used or disclosed without an authorization executed by the individual; and
- (8) A statement that an individual may elect to pay for health care from the individual's own funds and information on the right of such an individual to elect for identifying information not to be disclosed to anyone other than health care providers, unless such disclosure is required by mandatory reporting requirements or other similar information collection duties required by law.

Sec.103(b) Provision and Posting of Written Notice--A person described in subsection (a) shall provide a copy of the written notice of privacy practices at the time an authorization is sought for disclosure of protected health information; and upon the request of an individual. A person described in subsection (a) shall post, in a clear and conspicuous manner, a brief summary of the privacy practices of the person.

Sec.103(c) Model Notice--The Secretary, in consultation with the director of the Office of Health Information Privacy, after notice and opportunity for public comment, shall develop and disseminate model notices of privacy practices, and model summary notices for posting, for use under this section. Use of such a model notice shall be deemed to satisfy the requirements of this section.

### **Subtitle B-Establishment of Safeguards**

#### **Establishment of Safeguards**

Sec.111(a) In General--A health care provider, health plan, health oversight agency, public health authority, employer, health researcher, law enforcement official, health or life insurer, school, or university, or a person acting as the agent of any such person, shall establish and maintain appropriate administrative, organizational, technical, and physical safeguards and procedures to ensure the confidentiality, security, accuracy, and integrity of protected health information created, received, obtained, maintained, used, transmitted, or disposed of by such person.

Sec.111(b) Factors To Be Considered The policies and safeguards under subsection (a) shall ensure that (1) protected health information is used or disclosed only when necessary; (2) the categories of personnel who will have access to protected health information are identified; and (3) the feasibility of limiting access to protected health information is considered.

Sec.111(c) Model Guidelines The Secretary, in consultation with the Director of the Office of Health Information Privacy appointed under section 301, after notice and opportunity for public comment, shall develop and disseminate model guidelines for the establishment of safeguards and procedures for use under this section, such as, where appropriate, individual authentication of uses of computer systems, access controls, audit trails, encryption, physical security, protection of remote access points and protection of external electronic communications, periodic security assessments, incident reports, and

sanctions. The director shall update and disseminate the guidelines, as appropriate, to take advantage of new technologies.

### **Accounting for Disclosures**

**Sec. 112(a) In General**--A health care provider, health plan, health oversight agency, public health authority, employer, health researcher, law enforcement official, health or life insurer, school, or university, or a person acting as the agent of any such person, shall establish and maintain, with respect to any protected health information disclosure that is not related to payment or treatment, a record of the disclosure in accordance with regulations issued by the director of the Office of Health Information Privacy.

**Sec. 112(b) Maintenance of Record**--A record established under subsection (a) shall be maintained for not less than 7 years.

**Sec. 112(c) Electronic Records**--A health care provider, health plan, health oversight agency, public health authority, employer, health researcher, law enforcement official, health or life insurer, school, or university, or a person acting as the agent of any such person, shall, to the extent practicable, maintain an accessible electronic record concerning each access, or attempt to access, whether authorized or unauthorized, successful or unsuccessful, protected health information maintained by such person in electronic form. The record shall include the identity of the specific individual accessing or attempting to gain such access (or a way to identify that individual or information helpful in determining the identity of such individual), information sufficient to identify the protected health information sought or accessed, and other appropriate information.

## **TITLE II--RESTRICTIONS ON USE AND DISCLOSURE**

### **General Rules Regarding Use and Disclosure**

**Sec. 201(a) Prohibition**--A health care provider, health plan, health oversight agency, public health authority, employer, health researcher, law enforcement official, health or life insurer, school, or university may not disclose protected health information except as authorized under this Act. Disclosure of de-identified health information shall not be construed as a disclosure of protected health information.

**Sec. 201(b) Scope of Disclosure**--A disclosure of protected health information under this title shall be limited to the minimum amount of information necessary to accomplish the purpose for which the disclosure is made. The determination as to what constitutes the minimum disclosure possible for this purpose shall be made by the health care provider.

**Sec. 201(c) Use or Disclosure for Purpose Only**--A recipient of information pursuant to this title may use or disclose such information solely to carry out the purpose for which the information was disclosed.

**Sec. 201(d) No General Requirement To Disclose**--Nothing in this title permitting the disclosure of protected health information shall be construed to require such disclosure.

**Sec. 201(e) Identification of Disclosed Information as Protected Health Information**--Protected health information disclosed pursuant to this title shall be clearly identified as protected health information that is subject to this Act.

**Sec. 201(f) Disclosure by Agents**--An agent of a person described in subsection (a)(1), who receives

protected health information from the person while acting within the scope of the agency, shall be subject to this title to the same extent as the person and for the duration of the period in which the agent holds the information.

Sec. 201(g) Creation of De-Identified Information--Notwithstanding subsection (c), but subject to the other provisions of this section, a person described in subsection (a)(1) may disclose protected health information to an employee or other agent of the person for purposes of creating de-identified information.

Sec. 201(h) Unauthorized Use or Disclosure of the Decryption Key--The unauthorized disclosure of a decryption key shall be deemed to be a disclosure of protected health information. The unauthorized use of a decryption key or de-identified health information in order to identify an individual is deemed to be disclosure of protected health information.

Sec. 201(i) No Waiver--Except as provided in this Act, an authorization to disclose personally identifiable health information executed by an individual pursuant to section 202 or 203 shall not be construed as a waiver of any rights that the individual has under other Federal or State laws, the rules of evidence, or common law.

Sec. 201(j)(1) Definitions for the purpose of this title--Investigative or Law Enforcement Officer--The term "investigative or law enforcement officer" means any officer of the United States or of a State or political subdivision thereof, who is empowered by law to conduct investigations of, or to make arrests for, criminal offenses, and any attorney authorized by law to prosecute or participate in the prosecution of such offenses.

Sec. 201(j)(2) Definitions--Segregate--The term "segregate" means to place a designated subset of protected health information in a location or computer file that is separate from the location or computer file used to store protected health information and where access to or use of any information so segregated may be effectively limited to those individuals who are authorized to access or use such information.

Sec. 201(j)(3) Definition--Signed--The term "signed" refers to both signatures in ink and electronic signatures, and the term "written" refers to both paper and computerized formats.

## **AUTHORIZATIONS FOR DISCLOSURE OF**

### **PROTECTED HEALTH INFORMATION FOR TREATMENT AND PAYMENT.**

Sec. 202(a)(1) In General--To satisfy the requirement under section 201(a)(1), an employer, health plan, health or life insurer, or health care provider that seeks to disclose protected health information in connection with treatment or payment shall obtain an authorization that satisfies the requirements of this section. The authorization may be a single authorization.

Sec. 202(a)(2) Employers--Every employer offering a health plan to its employees shall, at the time of an employee's enrollment in the health plan, obtain a signed, written authorization that is a legal, informed authorization that satisfies the requirements of subsection (b) concerning the use and disclosure of protected health information for treatment or payment with respect to each individual who is eligible to receive care under the health plan.

Sec. 202(a)(3) Health plans, health or life insurers--Every health plan or health or life insurer offering

enrollment to individual or non-employer groups shall, at the time of enrollment in the plan or insurance, obtain a signed, written authorization that is a legal, informed authorization that satisfies the requirements of subsection (b) concerning the use and disclosure of protected health information with respect to each individual who is eligible to receive care under the plan or insurance.

Sec. 202(a)(4) Uninsured--An originating provider providing health care in other than a network plan setting, or providing health care to an uninsured individual, shall obtain a signed, written authorization that satisfies the requirements of subsection (b) to use protected health information in providing health care or arranging for health care from other providers or seeking payment for the provision of health care services.

Sec. 202(a)(5)(A) Providers--In General--Every health care provider providing health care to an individual who has not given the appropriate authorization under this section shall, at the time of providing such care, obtain a signed, written authorization that is a legal, informed authorization, that satisfies the requirements of subsection (b), concerning the use and disclosure of protected health information with respect to such individual.

Sec. 202(a)(5)(B) Providers--Rule of construction--Subparagraph (A) shall not be construed to preclude the provision of health care to an individual who has not given appropriate authorization prior to receipt of such care if the health care provider involved determines that such care is essential; and the individual can reasonably be expected to sign an authorization for such care when appropriate.

Sec. 202(b) Requirements for Individual Authorization--To satisfy the requirements of this subsection, an authorization to disclose protected health information shall:

- (1) identify, by general job description or other functional description, persons authorized to disclose the information;
- (2) describe the nature of the information to be disclosed;
- (3) shall identify, by general job description or other functional description, persons to whom the information is to be disclosed, including individuals employed by, or operating within, an entity to which information is authorized to be disclosed;
- (4) describe the purpose of the disclosures;
- (5) shall permit the executing individual to indicate that a particular individual listed on the authorization is not authorized to receive protected health information concerning the individual, except as provided for in subsection (c)(3);
- (6) shall provide the means by which an individual may indicate that some of the individual's protected health information should be segregated;
- (7) be subject to revocation by the individual and indicate that the authorization is valid until revocation by the individual or until an event or date specified; and
- (8) be in writing, dated, and signed by the individual; or in electronic form, dated and authenticated by the individual using a unique identifier; and shall not have been revoked.

Sec. 202(c)(1) Limitation on Authorizations--In General--Subject to paragraphs (2) and (3), a person



described in subsection (a) who seeks an authorization under such subsection may not condition the delivery of treatment or payment for services on the receipt of such an authorization.

Sec. 202(c)(2) Limitation on Authorizations Right to Require Self Payment--If an individual has refused to provide an authorization for disclosure of administrative billing information to a person and such authorization is necessary for a health care provider to receive payment for services delivered, the health care provider may require the individual to pay from their own funds for the services.

Sec. 202(c)(3) Limitation on Authorizations--Right of Health Care Provider to Require Authorization for Treatment Purposes □ If a health care provider that is seeking an authorization for disclosure of an individual's protected health information believes that the disclosure of such information is necessary so as not to endanger the health or treatment of the individual, the health care provider may condition the provision of services upon the execution of the authorization by the individual.

Sec. 202(d) Model Authorizations--The Secretary, after notice and opportunity for public comment, shall develop and disseminate model written authorizations of the type described in this section and model statements of the limitations on authorizations. Any authorization obtained on a model authorization form developed by the Secretary pursuant to the preceding sentence shall be deemed to satisfy the requirements of this section.

Sec. 202(e) Segregation of Files--A person described in subsection (a)(1) shall comply, to the maximum extent practicable, with the request of an individual who is the subject of protected health information to segregate any type or amount of protected health information, other than administrative billing information, held by the entity; or to limit the use or disclosure of the segregated health information within the entity to those persons specifically designated by the subject of the protected health information.

Sec. 202(f)(1) Revocation of Authorization. In General--An individual may in writing revoke or amend an authorization under this section at any time, unless the disclosure that is the subject of the authorization is required to effectuate payment for health care that has been provided to the individual.

Sec. 202(f)(2) Revocation of Authorization. Health plans--With respect to a health plan, the authorization of an individual is deemed to be revoked at the time of the cancellation or non-renewal of enrollment in the health plan, except as may be necessary to complete plan administration and payment requirements related to the individual's period of enrollment.

Sec. 202(f)(3) Revocation of Authorization. Actions--An individual may not maintain an action against a person for disclosure of personally identifiable health information if the disclosure was made based on a good faith reliance on the individual's authorization under this section at the time disclosure was made; in a case in which the authorization is revoked, if the disclosing person had no actual or constructive notice of the revocation; or if the disclosure was for the purpose of protecting another individual from imminent physical harm, and is authorized under section 204.

Sec. 202(g) Record of Individual's Authorizations and Revocations--Each person collecting or storing personally identifiable health information shall maintain a record for a period of 7 years of each authorization of an individual and any revocation thereof, and such record shall become part of the personally identifiable health information concerning such individual.

Sec. 202(h) Rule of Construction--Authorizations for the disclosure of protected health information for treatment or payment shall not authorize the disclosure of such information by an individual with the

intent to sell, transfer, or use protected health information for commercial advantage other than the revenues directly derived from the provision of health care to that individual. For such disclosures, a separate authorization that satisfies the requirements of section 203 is required.

### **AUTHORIZATIONS FOR DISCLOSURE OF PROTECTED HEALTH INFORMATION OTHER THAN FOR TREATMENT OR PAYMENT.**

Sec. 203(a) *In General*--To satisfy the requirement under section 201(a)(1), a health care provider, health plan, health oversight agency, public health authority, employer, health researcher, law enforcement official, health or life insurer, school, or university that seeks to disclose protected health information for a purpose other than treatment or payment may obtain an authorization that satisfies the requirements section 202(b). Such an authorization shall be separate from an authorization provided under section 202.

Sec. 203(b)(1) *Limitation on Authorizations*--A person subject to section 202 may not condition the delivery of treatment, or payment for services, on the receipt of an authorization described in this section.

Sec. 203(b)(2) *Limitation on Authorization Requirement for Separate Authorization*--A person subject to section 202 may not disclose protected health information to any employees or agents who are responsible for making employment, work assignment, or other personnel decisions with respect to the subject of the information without a separate authorization permitting such a disclosure.

Sec. 203(c) *Model Authorizations*--The Secretary, after notice and opportunity for public comment, shall develop and disseminate model written authorizations of the type described in subsection (a). Any authorization obtained on a model authorization form developed by the Secretary under this section shall be deemed to meet the authorization requirements of this section.

Sec. 203(d)(1) *Requirement To Release Protected Health Information to Coroners and Medical Examiners. In General*--When a Coroner or Medical Examiner or their duly appointed deputies seek protected health information for the purpose of inquiry into and determination of, the cause, manner, and circumstances of an individual's death, the health care provider, health plan, health oversight agency, public health authority, employer, health researcher, law enforcement officer, health or life insurer, school or university involved shall provide that individual's protected health information to the Coroner or Medical Examiner or to the duly appointed deputies without undue delay.

Sec. 203(d)(2) *Requirement To Release Protected Health Information to Coroners and Medical Examiners. Production of Additional Information*--If a Coroner or Medical Examiner or their duly appointed deputies receives health information from an entity referred to in paragraph (1), such health information shall remain as protected health information unless the health information is attached to or otherwise made a part of a Coroner's or Medical Examiner's official report, in which case it shall no longer be protected.

Sec. 203(d)(3) *Requirement To Release Protected Health Information to Coroners and Medical Examiners. Exemption*--Health information attached to or otherwise made a part of a Coroner's or Medical Examiner's official report, shall be exempt from the provisions of this Act except as provided for in this subsection.

Sec. 203(d)(4) Requirement To Release Protected Health Information to Coroners and Medical Examiners. Reimbursement--A Coroner or Medical Examiner may require a person to reimburse their Office for the reasonable costs associated with such inspection or copying.

Sec. 203(e) Revocation or Amendment of Authorization--An individual may, in writing, revoke or amend an authorization under this section at any time.

Sec. 203(f) Actions--An individual may not maintain an action against a person for disclosure of personally identifiable health information if the disclosure was made based on a good faith reliance on the individual's authorization under this section at the time disclosure was made; in a case in which the authorization is revoked, if the disclosing person had no actual or constructive notice of the revocation; or if the disclosure was for the purpose of protecting another individual from imminent physical harm, and is authorized under section 204.

### **Emergency Circumstances.**

Sec. 204(a) General Rule--In the event of a threat of imminent physical or mental harm to the subject of protected health information, any person may, in order to allay or remedy such threat, disclose protected health information about such subject to a health care practitioner, health care facility, law enforcement authority, or emergency medical personnel.

Sec. 204(b) Harm to Others--Any person may disclose protected health information about the subject of the information where such subject has made an identifiable threat of serious injury or death with respect to an identifiable individual or group of individuals; the subject has the ability to carry out such threat; and the release of such information is necessary to prevent or significantly reduce the possibility of such threat being carried out.

### **Public Health**

Sec. 205(a) Public Health. In General--A health care provider, health plan, public health authority, employer, health or life insurer, law enforcement official, school, or university may disclose protected health information to a public health authority or other person authorized by public health law when receipt of such information by the authority or other person if it:

- (1) relates directly to a specified public health purpose;
- (2) is reasonably likely to achieve such purpose; and
- (3) is intended for a purpose that cannot be achieved through the receipt or use of de-identified health information.

Sec. 205(b) Public Health Purpose Defined--For purposes of subsection (a), the term "public health purpose" means a population-based activity or individual effort, authorized by law, aimed at the prevention of injury, disease, or premature mortality, or the promotion of health, in a community, including assessing the health needs and status of the community through public health surveillance and epidemiological research; developing public health policy; responding to public health needs and emergencies; and any other activities or efforts authorized by law.

### **Protection and Advocacy Agencies**

Sec. 206 Any person who creates protected health information or receives protected health information under this title may disclose that information to a protection and advocacy agency established under part C of title I of the Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. 6041 et seq.) or under the Protection and Advocacy for Mentally Ill Individuals Act of 1986 (42 U.S.C. 10801 et seq.) when such agency can establish that there is probable cause to believe that an individual who is the subject of the protected health information is vulnerable to abuse and neglect by an entity providing health or social services to the individual.

### Oversight

Sec. 207(a) In General--A health care provider, health plan, employer, law enforcement official, health or life insurer, public health authority, health researcher, school or university may disclose protected health information to a health oversight agency to enable the agency to perform a health oversight function authorized by law, if:

- (1) the purpose for which the disclosure is to be made cannot reasonably be accomplished without protected health information;
- (2) the purpose for which the disclosure is to be made is of sufficient importance to warrant the effect on, or the risk to, the privacy of the individuals that additional exposure of the information might bring; and
- (3) there is a reasonable probability that the purpose of the disclosure will be accomplished.

Sec. 207(b) Use and Maintenance of Protected Health Information--A health oversight agency that receives protected health information under this section shall:

- (1) rely upon a unit record number contained in the file (or another formula) to scramble or otherwise safeguard, to the extent practicable, the identity of the subject of the protected health information in all documents summarizing the health oversight activity;
- (2) maintain in its records only such information about an individual as is relevant and necessary to accomplish the purpose for which the protected health information was obtained;
- (3) maintain such information securely and limit access to such information to those persons with a legitimate need for access to carry out the purpose for which the records were obtained; and
- (4) shall remove or destroy the information that allows subjects of protected health information to be identified at the earliest time at which removal or destruction can be accomplished, consistent with the purpose of the health oversight activity.

Sec. 207(c)(1) Use of Protected Health Information in Judicial Proceedings. In General--The disclosure and use of protected health information in any judicial, administrative, court, or other public, proceeding or investigation relating to a health oversight activity shall be undertaken in such a manner as to preserve the confidentiality and privacy of individuals who are the subject of the information, unless disclosure is required by the nature of the proceedings.

Sec. 207(c)(2) Use of Protected Health Information in Judicial Proceedings-- Limiting Disclosure--Whenever disclosure of the identity of the subject of protected health information is required by the nature of the proceedings, or it is impracticable to redact the identity of such individual, the agency shall

request that the presiding judicial or administrative officer enter an order limiting the disclosure of the identity of the subject to the extent possible, including the redacting of the protected health information from publicly disclosed or filed pleadings or records.

**Sec. 207(d) *Authorization by a Supervisor***--For purposes of this section, the individual with authority to authorize the oversight function involved shall provide to the disclosing person described in subsection (a) a statement that the protected health information is being sought for a legally authorized oversight function.

**Sec. 207(e) *Use in Action Against Individuals***--Protected health information about an individual that is disclosed under this section may not be used in, or disclosed to any person for use in, an administrative, civil, or criminal action or investigation directed against the individual, unless the action or investigation arises out of and is directly related to (1) the receipt of health care or payment for health care; (2) a fraudulent claim related to health; or (3) oversight of a public health authority or a health researcher.

## **DISCLOSURE FOR LAW ENFORCEMENT PURPOSES**

**Sec. 208(a) *Law Enforcement Access to Protected Health Information***--A health care provider, health researcher, health plan, health oversight agency, employer, health or life insurer, school, university, a person acting as the agent of any such person, or a person who receives protected health information pursuant to section 204, may disclose protected health information to an investigative or law enforcement officer pursuant to a warrant issued under the Federal Rules of Criminal Procedure, an equivalent State warrant, a grand jury subpoena, or a court order under limitations set forth in subsection (b).

**Sec. 208(b) *Requirements for Court Orders for Access to Protected Health Information***--A court order for the disclosure of protected health information under subsection (a) may be issued by any court that is a court of competent jurisdiction and shall issue only if the investigative or law enforcement officer submits a written application upon oath or equivalent affirmation demonstrating that there is probable cause to believe that:

- (1) the protected health information sought is relevant and material to an ongoing criminal investigation, except in the case of a State government authority, such a court order shall not issue if prohibited by the law of such State;
- (2) the investigative or evidentiary needs of the investigative or law enforcement officer cannot reasonably be satisfied by de-identified health information or by any other information; and
- (3) the law enforcement need for the information outweighs the privacy interest of the individual to whom the information pertains.

**Sec. 208(c) *Motions To Quash or Modify***--A court issuing an order pursuant to this section, on a motion made promptly by the health care provider, health researcher, health plan, health oversight agency, employer, health or life insurer, school, university, a person acting as the agent of any such person, or a person who receives protected health information pursuant to section 204, may quash or modify such order if the court finds that information or records requested are unreasonably voluminous or if compliance with such order otherwise would cause an unreasonable burden on such persons.

**Sec. 208(d)(1) *Notice. In General***--Except as provided in paragraph (2), no order for the disclosure of protected health information about an individual may be issued by a court under this section unless prior

notice of the application for the order has been served on the individual and the individual has been afforded an opportunity to oppose the issuance of the order.

Sec. 208(d)(2) Notice Not Required--An order for the disclosure of protected health information about an individual may be issued without prior notice to the individual if the court finds that notice would be impractical because (A) the name and address of the individual are unknown; or

(B) notice would risk destruction or unavailability of the evidence.

Sec. 208(e) Conditions--Upon the granting of an order for disclosure of protected health information under this section, the court shall impose appropriate safeguards to ensure the confidentiality of such information and to protect against unauthorized or improper use or disclosure.

Sec. 208(f) Limitation on Use and Disclosure for Other Law Enforcement Inquiries--Protected health information about an individual that is disclosed under this section may not be used in, or disclosed to any person for use in, any administrative, civil, or criminal action or investigation directed against the individual, unless the action or investigation arises out of, or is directly related to, the law enforcement inquiry for which the information was obtained.

Sec. 208(g) Destruction or Return of Information--When the matter or need for which protected health information was disclosed to an investigative or law enforcement officer or grand jury has concluded, including any derivative matters arising from such matter or need, the law enforcement agency or grand jury shall either destroy the protected health information, or return it to the person from whom it was obtained.

Sec. 208(h) Redactions--To the extent practicable, and consistent with the requirements of due process, a law enforcement agency shall redact personally identifying information from protected health information prior to the public disclosure of such protected information in a judicial or administrative proceeding.

Sec. 208(i) Exception □ This section shall not be construed to limit or restrict the ability of law enforcement authorities to gain information while in hot pursuit of a suspect or if other exigent circumstances exist.

## **NEXT OF KIN AND DIRECTORY INFORMATION.**

Sec. 209(a) Next of Kin--A health care provider, or a person who receives protected health information under section 204, may disclose protected health information about health care services provided to an individual to the individual's next of kin, or to another person whom the individual has identified, if at the time of the treatment of the individual:

- (1) the individual has: (A) been notified of the individual's right to object to such disclosure and the individual has not objected to the disclosure; or (B) is in a physical or mental condition such that the individual is not capable of objecting, and there are no prior indications that the individual would object; and
- (2) the information disclosed relates to health care services currently being provided to that individual.

Sec. 209(b)(1)(A) Directory Information. Disclosure. In General--Except as provided in paragraph (2),

with respect an individual who is admitted as an inpatient to a health care facility, a person described in subsection (a) may disclose information described in subparagraph (B) about the individual to any person if at the time of the admission, the individual:

- (i) has been notified of the individual's right to object and has not objected to the disclosure; or
- (ii) is in a physical or mental condition such that the individual is not capable of objecting and there are no prior indications that the individual would object.

Sec. 209(b)(1)(B) Directory Information. Information described in this subparagraph is information that consists only of 1 or more of the following items:

- (i) The name of the individual who is the subject of the information.
- (ii) The general health status of the individual, described as critical, poor, fair, stable, or satisfactory or in terms denoting similar conditions.
- (iii) The location of the individual within the health care facility to which the individual is admitted.

Sec. 209(b)(2) Directory Information. Exception--Paragraph (1)(B)(iii) shall not apply if disclosure of the location of the individual would reveal specific information about the physical or mental condition of the individual, unless the individual expressly authorizes such disclosure.

Sec. 209(c) Directory or Next-of-Kin Information--A disclosure may not be made under this section if the disclosing person described in subsection (a) has reason to believe that the disclosure of directory or next-of-kin information could lead to the physical or mental harm of the individual, unless the individual expressly authorizes such disclosure.

## **HEALTH RESEARCH**

Sec. 210(a) Regulations. In General--The requirements and protections provided for under part 46 of title 45, Code of Federal Regulations (as in effect on the date of enactment of this Act), shall apply to all health research. The shall not take effect until the Secretary has promulgated final regulations to implement this subsection.

Sec. 210(b) Regulations. Evaluation--Not later than 24 months after the date of enactment of this Act, the Secretary shall prepare and submit to Congress detailed recommendations on whether written informed consent should be required, and if so, under what circumstances, before protected health information can be used for health research.

Sec. 210(c) Recommendations--The recommendations required to be submitted under subsection (b) shall include:

- (1) a detailed explanation of current institutional review board practices, including the extent to which the privacy of individuals is taken into account as a factor before allowing waivers and under what circumstances informed consent is being waived;
- (2) a summary of how technology could be used to strip identifying data for the purposes of research;

- (3) an analysis of the risks and benefits of requiring informed consent versus the waiver of informed consent; and
- (4) an analysis of the risks and benefits of using protected health information for research purposes other than the health research project for which such information was obtained.
- (5) an analysis of the risks and benefits of allowing individuals to consent or to use consent, at the time of receiving medical treatment, to the possible future use of records of medical treatments for research studies.

Sec. 210(d) Consultation--In carrying out this section, the Secretary shall consult with individuals who have distinguished themselves in the fields of health research, privacy, related technology, consumer interests in health information, health data standards, and the provision of health services.

Sec. 210(e) Congressional Notice--Not later than 6 months after the date on which the Secretary submits to Congress the recommendations required under subsection (b), the Secretary shall propose to implement such recommendations through regulations promulgated on the record after opportunity for a hearing, and shall advise the Congress of such proposal.

Sec. 210(f)(1) Other Requirements. Obligations of the recipient--A person who receives protected health information pursuant to this section shall remove or destroy, at the earliest opportunity consistent with the purposes of the project involved, information that would enable an individual to be identified, unless an institutional review board has determined that there is a health or research justification for the retention of such identifiers; and there is an adequate plan to protect the identifiers from disclosure consistent with this section; and

Sec. 210(f)(2) Other Requirements. Periodic Review and Technical Assistance--Any institutional review board that authorizes research under this section shall provide the Secretary with the names and addresses of the institutional review board members. The Secretary may provide technical assistance to institutional review boards described in this subsection. The Secretary shall periodically monitor institutional review boards described in this subsection. Not later than 3 years after the date of enactment of this Act, the Secretary shall report to Congress regarding the activities of institutional review boards described in this subsection.

Sec. 210(g) Limitation--Nothing in this section shall be construed to permit protected health information that is received by a researcher under this section to be accessed for purposes other than research or as authorized by the individual.

## **JUDICIAL AND ADMINISTRATIVE PURPOSES.**

Sec. 211(a) In General a health care provider, health plan, health oversight agency, employer, insurer, health or life insurer, school or university, a person acting as the agent of any such person, or a person who receives protected health information under section 204, may disclose protected health information:

- (1) pursuant to the standards and procedures established in the Federal Rules of Civil Procedure or comparable rules of other courts or administrative agencies, in connection with litigation or proceedings to which an individual who is the subject of the information is a party and in which the individual has placed his or her physical or mental condition at issue;
- (2) to a court, and to others ordered by the court, if in response to a court order issued by a court



of competent jurisdiction in accordance with subsections (b) and (c); or

- (3) if necessary to present to a court an application regarding the provision of treatment of an individual or the appointment of a guardian.

**Sec.211(b) Court Orders for Access to Protected Health Information**--A court order for the disclosure of protected health information under subsection (a) may be issued only if the person seeking disclosure submits a written application upon oath or equivalent affirmation demonstrating by clear and convincing evidence that:

- (1) the protected health information sought is necessary for the adjudication of a material fact in dispute in a civil proceeding;
- (2) the adjudicative need cannot be reasonably satisfied by de-identified health information or by any other information; and
- (3) the need for the information outweighs the privacy interest of the individual to whom the information pertains.

**Sec.211(c)(1) Notice. In General**--Except as provided in paragraph (2), no order for the disclosure of protected health information about an individual may be issued by a court unless notice of the application for the order has been served on the individual and the individual has been afforded an opportunity to oppose the issuance of the order.

**Sec.211(c)(2) Notice. Notice Not Required**--An order for the disclosure of protected health information about an individual may be issued without notice to the individual if the court finds, by clear and convincing evidence, that (1) notice would be impractical because the name and address of the individual are unknown; or (2) notice would risk destruction or unavailability of the evidence.

**Sec. 211(d) Obligations of Recipient.** - A person seeking protected health information pursuant to subsection (a)(1) shall: (1) notify the individual or the individual's attorney of the request for the information; (2) provide the health care provider, health plan, health oversight agency, employer, insurer, health or life insurer, school or university, agent, or other person involved with a signed document attesting that the individual has placed his or her physical or mental condition at issue in litigation or proceedings in which the individual is a party; and the date on which the individual or the individual's attorney was notified under paragraph (1); and (3) not accept any requested protected health information from the health care provider, health plan, health oversight agency, employer, insurer, health or life insurer, school or university, agent, or person until the termination of the 10-day period beginning on the date notice was given under paragraph (1).

## **INDIVIDUAL REPRESENTATIVES**

**Sec. 212(a) In General**--Except as provided in subsections (b) and (c), a person who is authorized by law (based on grounds other than an individual's status as a minor), or by an instrument recognized under law, to act as an agent, attorney, proxy, or other legal representative of a individual, may, to the extent so authorized, exercise and discharge the rights of the individual under this Act.

**Sec. 212(b) Health Care Power of Attorney**--A person who is authorized by law (based on grounds other than being a minor), or by an instrument recognized under law, to make decisions about the provision of health care to an individual who is incapacitated, may exercise and discharge the rights of the individual

under this Act to the extent necessary to effectuate the terms or purposes of the grant of authority.

Sec .212(c) No Court Declaration--If a physician or other health care provider determines that an individual, who has not been declared to be legally incompetent, suffers from a medical condition that prevents the individual from acting knowingly or effectively on the individual's own behalf, the right of the individual to authorize disclosure under this Act may be exercised and discharged in the best interest of the individual by a person described in subsection (b) with respect to the individual; a person described in subsection (a) with respect to the individual, but only if a person described in paragraph (1) cannot be contacted after a reasonable effort; the next of kin of the individual, but only if a person described in paragraph (1) or (2) cannot be contacted after a reasonable effort; or the health care provider, but only if a person described in paragraph (1), (2), or (3) cannot be contacted after a reasonable effort.

Sec. 209(d) Rights of Minors--For individuals who are 18 years of age or older all rights of the individual under this Act shall be exercised by the individual; or who, acting alone, can obtain a type of health care without violating any applicable law, and who has sought such care, the individual shall exercise all rights of an individual under this Act with respect to protected health information relating to such health care. In the case of individuals under 14 years of age, all of the individual's rights under this Act shall be exercised through the parent or legal guardian; or through 17 years of age, the rights of inspection and supplementation, and the right to authorize use and disclosure of protected health information of the individual shall be exercised by the individual, or by the parent or legal guardian of the individual.

Sec .212(e)(1) Application to Deceased Individuals--The provisions of this Act shall: (1) continue to apply to protected health information concerning a deceased individual;

Sec. 212(e)(2) Exercise of Rights on Behalf of a Deceased Individual--A person who is authorized by law or by an instrument recognized under law, to act as an executor of the estate of a deceased individual, or otherwise to exercise the rights of the deceased individual, may, to the extent so authorized, exercise and discharge the rights of such deceased individual under this Act for a period of 2 years following the death of that individual. If no such designee has been authorized, the rights of the deceased individual may be exercised as provided for in subsection (c).

Sec .212(e)(3) Application to Deceased Individuals--The provisions of this Act shall continue to apply to protected health information concerning a deceased individual for a period of 2 years following the death of that individual.

### **PROHIBITION AGAINST RETALIATION**

Sec.213 A health care provider, health researcher, health plan, health oversight agency, employer, health or life insurer, school or university, person acting as an agent of any such person, or person who receives protected health information under section 204 may not adversely affect another person, directly or indirectly, because such person has exercised a right under this Act, disclosed information relating to a possible violation of this Act, or associated with, or assisted, a person in the exercise of a right under this Act.

## **TITLE III**

### **OFFICE OF HEALTH INFORMATION PRIVACY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Subtitle A DESIGNATION.**

**Sec. 301(a) *Designation-In General*** The Secretary shall designate an office within the Department of Health and Human Services to be known as the Office of Health Information Privacy. The Office shall be headed by a Director, who shall be appointed by the Secretary.

**Sec. 301(b) *Duties***--The Director of the Office of Health Information Privacy shall receive and investigate complaints of alleged violations of this Act; provide for the conduct of audits where appropriate; provide guidance to the Secretary in the implementation of this Act; prepare and submit the report described in subsection (c); consult with, and provide recommendation to, the Secretary concerning improvements in the privacy and security of protected health information and concerning medical privacy research needs; and carry out any other activities determined appropriate by the Secretary.

**Sec. 301(c) *Report on Compliance***--Not later than January 1 of the first calendar year beginning more than 1 year after the establishment of the Office under subsection (a), and every January 1 thereafter, the Director of the Office of Health Information Privacy shall prepare and submit to Congress a report concerning the number of complaints of alleged violations of this Act that are received during the year for which the report is being prepared. Such report shall describe the complaints and any remedial action taken concerning such complaints.

**Subtitle B--Enforcement****CHAPTER 1 CRIMINAL PROVISIONS****WRONGFUL DISCLOSURE OF PROTECTED HEALTH INFORMATION**

**Sec. 311.** This section amends Part I of title 18, United States Code. The amendment provides that a person that knowingly and intentionally obtains or discloses protected health information relating to an individual in violation of title II of this Act shall be amended by adding at the end the following: (1) be fined not more than \$50,000, imprisoned not more than 1 year, or both; (2) if the offense is committed under false pretenses, be fined not more than \$250,000, imprisoned not more than 5 years, or any combination of such penalties; or (3) if the offense is committed with the intent to sell, transfer, or use protected health information for commercial advantage, personal gain, or malicious harm, be fined not more than \$500,000, imprisoned not more than 10 years, excluded from participation in any Federally funded health care programs, or any combination of such penalties. These penalties shall be doubled for every subsequent violation.

**DEBARMENT FOR CRIMES.**

**Sec. 312(a) *Purpose***--The purpose of this section is to promote the prevention and deterrence of instances of intentional criminal actions which violate criminal laws which are designed to protect the privacy of protected health information in a manner consistent with this Act.

**Sec. 312(b) *Debarment***--Not later than 270 days after the date of enactment of this Act, the Attorney General, in consultation with the Secretary, shall promulgate regulations and establish procedures to permit the debarment of health care providers, health researchers, health or life insurers, or schools or universities from receiving benefits under any Federal health programs or other Federal procurement

programs if the managers or officers of such persons are found guilty of violating section 2801 of title 18, United States Code, found liable in any civil or administrative proceeding concerning the illegal disclosure of protected health information, or are found guilty of making a false statement or obstructing justice related to attempting to conceal or concealing such illegal disclosure.

Such regulations shall take into account the need for continuity of medical care and may provide for a delay of any debarment imposed under this section to take into account the medical needs of patients.

Sec. 312(c) Consultation--Before publishing a proposed rule to implement subsection (b), the Attorney General shall consult with State law enforcement officials, health care providers, patient privacy rights' advocates, and other appropriate persons, to gain additional information regarding the debarment of entities under subsection (b) and the best methods to ensure the continuity of medical care.

Sec. 312(d) Report--The Attorney General shall annually prepare and submit to the Committee on the Judiciary of the House of Representatives and the Committee on the Judiciary of the Senate a report concerning the activities and debarment actions taken by the Attorney General under this section.

Sec. 312(e) Assistance To Prevent Criminal Violations--The Attorney General, in cooperation with any other appropriate individual, organization, or agency, may provide advice, training, technical assistance, and guidance regarding ways to reduce the incidence of improper disclosure of protected health information.

Sec. 312(f) Relationship to Other Authorities--A debarment imposed under this section shall not reduce or diminish the authority of a Federal, State, or local governmental agency or court to penalize, imprison, fine, suspend, debar, or take other adverse action against a person, in a civil, criminal, or administrative proceeding.

## CHAPTER 2-CIVIL SANCTIONS

Sec. 321(a) Civil Penalty. Violation--Where the Secretary, in consultation with the Attorney General, determines that a person has substantially and materially failed to comply with this Act, in addition to any other penalties that may be prescribed by law shall be subject (1) in a case in which the violation relates to title I, to a civil penalty of not more than \$500 for each such violation, but not to exceed \$5000 in the aggregate for multiple violations; (2) in a case in which the violation relates to title II, to a civil penalty of not more than \$10,000 for each such violation, but not to exceed \$50,000 in the aggregate for multiple violations; or (3) in a case in which the Secretary finds that such violations have occurred with such frequency as to constitute a general business practice, to a civil penalty of not more than \$100,000.

Sec. 321(b) Civil Penalty. Procedures for Imposition of Penalties--Section 1128A of the Social Security Act (42 U.S.C. 1320a-7a), other than subsections (a) and (b) and the second sentence of subsection (f) of that section, shall apply to the imposition of a civil, monetary, or exclusionary penalty under this section in the same manner as such provisions apply with respect to the imposition of a penalty under section 1128A of such Act.

## PROCEDURES FOR IMPOSITION OF PENALTIES

Sec. 322 Initiation of Proceedings. In General--The Secretary, in consultation with the Attorney General, may initiate a proceeding to determine whether to impose a civil money penalty. [*The rest of this section outlines the procedures that must be followed in order to impose a civil penalty.*]

## **CIVIL ACTION BY INDIVIDUALS**

**Sec. 323(a) In General**--Any individual whose rights under this Act have been knowingly or negligently violated may bring a civil action to recover such preliminary and equitable relief as the court determines to be appropriate; and the greater of compensatory damages or liquidated damages of \$5,000.

**Sec. 323(b) Punitive Damages**--In any action brought under this section in which the individual has prevailed because of a knowing violation of a provision of this Act, the court may, in addition to any relief awarded under subsection (a), award such punitive damages as may be warranted.

**Sec. 323(c) Attorney's Fees**--In the case of a civil action brought under subsection (a) in which the individual has substantially prevailed, the court may assess against the respondent a reasonable attorney's fee and other litigation costs and expenses (including expert fees) reasonably incurred.

**Sec. 323(d) Limitation**--No action may be commenced under this section more than 3 years after the date on which the violation was or should reasonably have been discovered.

**Sec. 323(e) Agency** A principal is jointly and severally liable with the principal's agent for damages under this section for the actions of the principal's agent acting within the scope of the agency.

**Sec. 323(f) Additional Remedies** The equitable relief or damages that may be available under this section shall be in addition to any other lawful remedy or award available.

## **TITLE IV-MISCELLANEOUS**

### **RELATIONSHIP TO OTHER LAWS.**

**Sec. 401(a) Federal and State Laws**--Nothing in this Act shall be construed as preempting, superseding, or repealing, explicitly or implicitly, other Federal or State laws or regulations relating to protected health information or relating to an individual's access to protected health information or health care services, if such laws or regulations provide protections for the rights of individuals to the privacy of, and access to, their health information that are greater than those provided for in this Act.

**Sec. 401(b) Privileges**--Nothing in this Act shall be construed to preempt or modify any provisions of State statutory or common law to the extent that such law concerns a privilege of a witness or person in a court of that State. This Act shall not be construed to supersede or modify any provision of Federal statutory or common law to the extent such law concerns a privilege of a witness or person in a court of the United States. Authorizations pursuant to section 202 shall not be construed as a waiver of any such privilege.

**Sec. 401(c) Certain Duties Under Law**--Nothing in this Act shall be construed to preempt, supersede, or modify the operation of any State law that provides for the reporting of vital statistics such as birth or death information; requires the reporting of abuse or neglect information about any individual; regulates the disclosure or reporting of information concerning an individual's mental health; or governs a minor's rights to access protected health information or health care services.

**Sec. 401(d) Federal Privacy Act**--The Federal Privacy Act is amended to allow for the promulgation of rules in accordance with this Act.

**Sec. 401(e) Constitution**--Nothing in this Act shall be construed to alter, diminish, or otherwise weaken

existing legal standards under the Constitution regarding the confidentiality of protected health information.

#### **EFFECTIVE DATE**

**Sec. 402 *Effective Date***--Unless specifically provided for otherwise, this Act shall take effect on the date that is 12 months after the date of the promulgation of the regulations required under subsection (b), or 30 months after the date of enactment of this Act, whichever is earlier. Not later than 12 months after the date of enactment of this Act, or as specifically provided for otherwise, the Secretary shall promulgate regulations implementing this Act.